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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,233	10/24/2003	Zehra Kaymakcalan	BBC-193	1420

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EXAMINER

CHAUDHURI, ANIRUDDHO RAY

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,233	KAYMAKCALAN ET AL.	
	Examiner	Art Unit	
	Aniruddho R Chaudhuri	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. For examination purposes the following is noted:

Groups I and II encompass methods of treatment, which employ separate and distinct products (antibody versus Etanercept, a dimeric soluble receptor). Antibodies and receptor molecules differ with respect to their structure, and modes of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

It appears that the only TNF- α inhibitors disclosed in the specification as filed are anti-TNF- α antibodies and Etanercept, a dimeric soluble receptor, see page 5, ¶ 1. Therefore the claims have been restricted according to these patentably distinct classes of inhibitors. Alternatively, if applicant intends to claim additional TNF- α inhibitors disclosed in the specification as filed, then such inhibitors would be subject to further restrictions.

If additional structurally distinct "agents" are introduced during the course of prosecution that do not share *a substantial structural feature essential to a common utility* with the instantly recited "agents", then a supplemental restriction requirement may be issued.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-31, drawn to a method of treating a disorder with an anti-TNF- α antibody, classified in Class 424, subclass 130.1.
 - II. Claims 1-4, 6-11, 13-17, 19-24, 26-29 and 31, drawn to a method of treating a disorder with Etanercept, classified in Class 424, subclass 192.1.

3. Groups I and II are different methods. These inventions are different with respect to ingredients and method steps, which require non-coextensive searches; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for an examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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Species Election

5. This application contains claims directed to the following patentably distinct species of the claimed Groups I and II wherein the disorder is selected from the following:

- a. sepsis,
- b. autoimmune disease,
- c. infectious disease,
- d. transplantation,
- e. malignancy,
- f. pulmonary disorder,
- g. intestinal disorder,
- h. cardiac disorder,
- i. neurological disorder,
- j. metabolic disease,
- k. liver disease,
- l. inflammatory disease,
- m. degenerative bone and joint disease,
- n. reperfusion injury, or
- o. other diseases or conditions disclosed on pages 15-16 of the instant specification.

Applicant is required to elect a species from "a-o" and in addition a specific species disclosed in the specification, e.g. see pages 8-16, as it reads on the elected species (e.g. autoimmune disease, rheumatoid arthritis).

It is noted that pages 8-16 of the instant specification discloses a number of disease and conditions that are encompassed by the claimed methods.

In addition, there appears to be overlap in the classification of the diseases (e.g. diabetes).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aniruddho Ray Chaudhuri whose telephone number is 571-272-0953. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Aniruddho Ray Chaudhuri (AC), Ph.D.
Patent Examiner
Technology Center 1600
October 4, 2004

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PRIMARY EXAMINER

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10/5/04